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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,808	12/07/2001	H. William Bosch	029318-0799	8203
31049	7590	03/31/2006	EXAMINER	
ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 03/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,808

Applicant(s)

BOSCH ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-76 and 93-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-76 and 93-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 16-38, 51-76, 93-104 and 107-110 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. US 5,565,188.

Wong discloses a composition containing nanoparticles comprising a therapeutic agent, and a surface modifier adsorbed to the surface of the nanoparticles (see abstract; and column 1, lines 51-67). Therapeutic agent is in a discrete crystalline phase, and can include a wide variety of drug including naproxen (column 3, lines 67 through column 4, lines 1-67; and column 5, line 9). Wong also teaches therapeutic agent having particle size of less than about 100 μm , or particles can be reduced to average particle size of less than 400 nm (column 5, lines 50-59; column 6, lines 7-9; and column 10, lines 1-15). Therapeutic is dispersed in at least one liquid medium, such as water or safflower oil (column 4, lines 4-19). Surface modifier includes cationic surface modifier, such as sodium dodecyl sulfate, dioctylsulfosuccinate, or dodecyltrimethylammonium bromide (column 11, lines 10-16). Surface modifier can be present in an amount of 0.1-90% (column 13, lines 25-31). The composition further comprises other excipients, and can be incorporated into dosage form suitable for rectal, vaginal, and topical administration including dry powder formulation (column 12,

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lines 48-64; and column 14, lines 5-13). Wong further discloses the use of additional surface modifier (column 9, lines 17-19).

It is noted that Wong is silent as to the teaching that the therapeutic is liquid at room temperature. However, it is the position of the examiner that the therapeutic taught by Wong would be liquid at room temperature, because Wong teaches the use of the same active agent, e.g., naproxen. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-38, 51-76, 93-104 and 107-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. US 5,565,188, in view of Pace et al. US 6,177,103.

Wong is relied upon for the reason stated above. In the case that applicant can overcome the 102(b) rejection, the 13(a) rejection is relied upon for the following reason.

Pace teaches the use of combination of surface modifiers including benzalkonium chloride (column 6, line 53). Thus, it would have been obvious to one of ordinary skill in the art to modify the nanoparticles of Wong using the surface modifiers in view of the teaching of Pace to obtain the claimed invention, because Pace teaches the use of cationic surfactants suitable for poorly soluble therapeutic compound (columns 5-6), because Pace teaches the use of similar therapeutic compound used by Wong, and because Wong teaches the use of surface modifier having rheological properties that produced a nanoparticles composition useful as bioadhesive and/or control release agents for the delivery of therapeutic agents (column 3, lines 30-49).

Claims 39-50, 105 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. US 5,565,188, in view of Mantelle et al. US 6,316,022 and Wik US 5,938,017.

Wong is relied upon for the reasons stated above. Wong does not teach water-soluble active agent.

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Mantelle teaches a transdermal composition comprising low molecular weight drug that is liquid at room temperature including pesticides, sunscreen and cosmetic agent (column 4, lines 34-58). Mantelle also teaches water-soluble active agent such as nicotine (column 5, lines 12-18; see also Wik at column 7, line 60 (for the teaching that nicotine is water-soluble)). The composition further comprises enhancers (surface modifier), and co-solvents such as mineral oil, or alcohol (column 5, lines 66 through column 6, lines 1-39). Thus, it would have been obvious to one of ordinary skill in the art to modify the nanoparticles of Wong for the active agents in view of the teaching of Mantelle, because Wong teaches a nanoparticles composition suitable for a variety of therapeutic agents, and because Mantelle teaches water-soluble therapeutic active agent can be prepared for topical administration.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Scholz et al., and Liversidge et al. are cited as of interest for the teachings of surface modifier drug nanoparticles.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600